

NORTH  
COUNTY  
NEUROSURGERY,  
INCORPORATED

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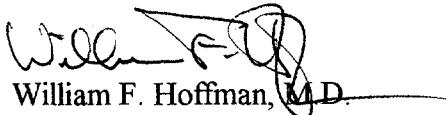
Document Management Branch (H.F.A.-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 106 1  
Rockville, MD 20852

Re: Docket No. 97N-484S

Dear Sir:

This letter is being sent to you to encourage you to not proceed with the proposed FDA regulation that will treat **allograft** as a medical device. I have been in neurosurgical practice for over twenty years and have used **allograft** bone literally ~~thousand~~ of times. As of yet, I have not had a single complication related to transmissible disease or other problems that would make me feel this needed to be handled as a medical device. In addition, it has saved patients a tremendous amount of pain and suffering by avoiding bone harvest. It has helped many patients with reduced pain and increased mobility. If there is such an undertaking by the FDA, it would most likely remove the ability to provide help for our patients using allograft bone. This would not be acceptable.

Sincerely

  
William F. Hoffman, M.D.

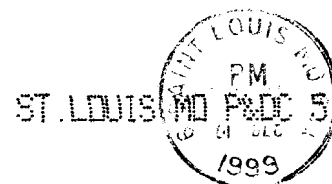
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